

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
)  
Cara A. PELLEGRINI *et al.* ) Parent Group Art Unit: 1617  
)  
Continuation-in-Part of Application No.: ) Parent Examiner: Theodore J.  
09/994,837 ) CRIARES  
)  
Filed: August 22, 2003 )  
)  
For: METHOD OF INCREASING THE )  
EXTENT OF ABSORPTION OF )  
TIZANIDINE )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents that were previously submitted in a prior application, Application No. 09/994,837, filed November 28, 2001, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120, are not provided herewith. Applicants respectfully request that the Examiner consider these listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

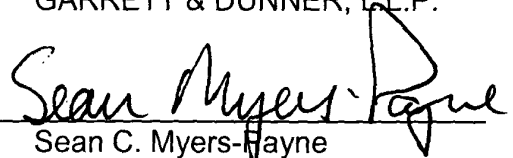
If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 22, 2003

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## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	8576.0012-01	Appln. No	Unassigned.
Applicant	Cara A. PELLEGRINI <i>et al.</i>		
Filing Date	August XX, 2003	Group:	Unassigned

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	3,843,668	10/22/74	Neumann			
	4,053,617	10/11/77	Eichenberger et al.			
	5,837,285	Nov. 17, 1998	Nakamichi et al.	424	464	
	5,977,175	Nov. 2, 1999	Lin	514	558	
	5,980,927	11/9/99	Nelson et al.			
	6,110,494	Aug. 29, 2000	Clancy et al.	424	461	
	6,143,325	Nov. 7, 2000	Dennis et al.	424	468	
	6,214,370	4/10/01	Nelson et al.			
	6,248,363 B1	Jun. 19, 2001	Patel et al.	424	497	
	6,268,389 B1	Jul. 31, 2001	Esser et al.	514	398	
	6,342,245 B1	Jan. 29, 2002	Baert et al.	424	451	April 24, 2000
	2001/0007678A1	Jul. 12, 2001	Baert et al.	424	464	
	2001/0024659A1	Sep. 27, 2001	Chen et al.	424	457	
	2002/0006919A1	Jan. 17, 2002	Thosar et al.	514	175	

FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	"Tizanidine," <a href="http://www.virtualdrugstore.com/ms/tizanidine.html">http://www.virtualdrugstore.com/ms/tizanidine.html</a>
	"Pharmacology," <a href="http://www.southshoreneurologic.com/spas-manag/spas-pharmacology.html">http://www.southshoreneurologic.com/spas-manag/spas-pharmacology.html</a>
	"Spasticity," <a href="http://www.wemove.org/spa_mtop.html">http://www.wemove.org/spa_mtop.html</a>
	Wagstaff et al., Tizanidine, "A Review of its Pharmacology, Clinical Efficacy and Tolerability in the Management of Spasticity Associated with Cerebral and Spinal Disorders," ADIS Drug Evaluation, Drugs, 53(3), pp. 435-452 (March 1997)
	Zanaflex®, 2001 Physicians' Desk Reference (2001)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	The Merck Index (1989)
	Wesnes et al., "Effects of Sibutramine alone and with alcohol on cognitive function in healthy volunteers," <i>British Journal of Clinical Pharmacology</i> , 49, pp. 110-117 (2000)
	Simpson et al., "The Cognitive Drug Research Computerized Assessment System for Demented Patients: A Validation Study, <i>International Journal of Geriatric Psychiatry</i> ," <i>International Journal of Geriatric Psychiatry</i> , Vol. 6, pp. 95-102 (1991)
	Chapleo et al., "Heteroaromatic Analogues of the $\alpha_2$ -Adrenoreceptor Partial Agonist Clonidine," <i>J. Med. Chem</i> , 32, pp. 1627-1630 (1989)
	Smith et al., "Tizanidine in the management of spasticity and musculoskeletal complaints in the palliative care population, <i>American Journal of Hospice &amp; Palliative Care</i> ," <i>American Journal of Hospice &amp; Palliative Care</i> , 17(1), pp. 50-58 (Jan-Feb. 2000)
	Hutchinson, D. E., Modified Release of Tizanidine, A Review; Volume 17, No. 5 pp. 565-573 (1989)
	Holtebeck, B., "Tizanidine: An alternative in the Pharmacologic Treatment of Spasticity," <i>Journal of the Pharmacy Society of Wisconsin</i> , Mar/Apr 2000: 26-31 (2000).
	Young, R., "Tizanidine and spasticity," <i>Neurology</i> 45(12): 2296-2296 (1995).
	Roberts, R.C., et al., "Pharmacokinetics and pharmacodynamics of tizanidine," <i>Neurology</i> 44(Supp 9): S29-S31 (1994).
	Wallace, J.D., "Summary of combined clinical trials analysis of controlled clinical trials with tizanidine," <i>Neurology</i> 44(Supp 9): S60-S68 (1994).
	Shellenberger, M.K., et al., "A controlled pharmacokinetic evaluation of tizanidine and baclofen at steady state," <i>Drug Metabolism and Distribution</i> 27(2): 201-204 (1999).

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce